

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF GEORGIA  
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004 4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
LIABILITY LITIGATION	*	Case Nos. 4:12-cv-245 (Clinton) 4:12-cv-252 (Woolf)

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O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiffs Andrea Clinton and Bobbie Jo Woolf were implanted with ObTape and assert that they suffered injuries caused by ObTape. Each Plaintiff brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Plaintiffs also assert that Mentor did not adequately warn their physicians about the risks associated with ObTape. Mentor seeks summary judgment on several of Plaintiffs' claims. For the reasons set forth below, Mentor's partial summary judgment motions are is granted in part and denied in part.

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R.

Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

#### FACTUAL BACKGROUND

##### **I. Andrea Clinton (ECF No. 49 in 4:12-cv-245)**

Plaintiff Andrea Clinton visited Dr. John Saba for treatment of stress urinary incontinence. Dr. Saba recommended a sling implant, and he showed Clinton a "binder" of materials regarding the procedure. Clinton Dep. 87:9-16, ECF No. 50-3. The binder contained a diagram of the female anatomy and explained the basics of the transobturator process. *Id.* at 88:2-20. It also stated that "there was a chance of rare infection." *Id.* at 87:23-25. Clinton decided to go ahead with the sling procedure, and Dr. Saba implanted Clinton with ObTape on December 2, 2004.

In 2005, Clinton had severe left groin and leg pain, and she visited multiple physicians for treatment of these symptoms. None of the doctors connected the symptoms to Clinton's ObTape.

One of the doctors Clinton visited was Dr. John Mazuski, a general surgeon with a specialty in infectious disease. Like the other doctors, Dr. Mazuski did not connect Clinton's symptoms to her ObTape, and it is not clear from the present record whether Dr. Mazuski even knew that Clinton had been implanted with ObTape when he treated her in 2005. Dr. Mazuski testified that if Mentor had provided information to him clearly associating ObTape with a problem in the thigh and if he knew that Clinton had been implanted with ObTape, then he would have known that it was "at least an option" to remove the ObTape. Mazuski Dep. 92:6-93:6, ECF No. 50-3. Dr. Mazuski is not a urologist or a gynecologist, and he has no expertise in urology or gynecology. Mazuski Dep. 13:3-16, ECF No. 51-3. Dr. Mazuski has no clinical experience with suburethral slings like ObTape. *Id.* 68:5-20, ECF No. 51-3.

In December 2007, Clinton went to the hospital complaining of groin pain and swelling, as well as foul-smelling vaginal discharge. She also said that she could feel the ObTape in her vagina. Dr. Arnold Bullock diagnosed Clinton with an infection of her ObTape and a vaginal erosion, and he told her that she needed to have a revision surgery. Dr. Bullock performed a revision surgery on December 24, 2007, and he removed as much of the ObTape as he could. Clinton went back to Dr. Bullock with additional complaints, and he performed a second revision

surgery to remove additional ObTape from Clinton's body. Clinton's adverse symptoms continued, and Dr. Bullock performed exploratory surgery in February 2008 but could not find any additional tape. Clinton then visited Dr. Carl Klutke, who performed a fourth revision surgery in March 2008 and removed additional infected pieces of ObTape from Clinton's body. Clinton's symptoms improved after the fourth revision surgery. During each revision surgery, both Dr. Bullock and Dr. Klutke attempted to remove as much of the ObTape as possible.

Clinton is a Missouri resident whose ObTape-related treatment took place in Missouri. She filed her action in this Court pursuant to the Court's direct filing order on September 20, 2012, asserting claims for negligence, strict liability - design defect, strict liability - manufacturing defect, strict liability - failure to warn, breach of implied warranties, breach of express warranties, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation.

## **II. Bobbie Jo Woolf (ECF No. 43 in 4:12-cv-252)**

Dr. Carl Klutke diagnosed Plaintiff Bobbie Jo Woolf with stress urinary incontinence. Dr. Klutke testified that he would have shared information from the ObTape product data insert sheet with patients like Woolf. Klutke Dep. 33:10-16, ECF No. 44-3. The product information sheet states that the risk of certain complications is very rare. Woolf testified that if Dr.

Klutke had told her that the risks were not very rare or that she could develop complications years after the surgery, she would not have consented to the ObTape procedure. Woolf Dep. 120:1-121:8, ECF No. 44-3.

Dr. Klutke implanted Woolf with ObTape on December 9, 2004. After the procedure, Woolf's urinary leakage improved, but it returned in mid-2007. And in November 2008, after Woolf began experiencing vaginal discomfort, Woolf saw Dr. Salina Green. Dr. Green told Woolf that "mesh had fallen and was growing inside" her. Woolf Dep. 97:3-5. Woolf was referred to Dr. Dionysios Veronikis, who recommended surgical removal of Woolf's ObTape. On January 6, 2009, Dr. Veronikis removed as much of the ObTape as he could.

Woolf is a Missouri resident whose ObTape-related treatment took place in Missouri. She filed her action in this Court pursuant to the Court's direct filing order on September 20, 2012, asserting claims for negligence, strict liability - design defect, strict liability - manufacturing defect, strict liability - failure to warn, breach of implied warranties, breach of express warranties, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation. Woolf does not contest summary judgment as to her claims for breach of implied warranty, fraudulent misrepresentation, and negligent

misrepresentation, so Mentor's partial summary judgment motion is granted as to those claims.

#### DISCUSSION

Clinton and Woolf filed their actions in this Court under the Court's direct filing order. The parties agreed that for direct-filed cases, the "Court will apply the choice of law rules of the state where the plaintiff resides at the time of the filing of the complaint." Order Regarding Direct Filing § II(E), ECF No. 446 in 4:08-md-2004. Clinton and Woolf are Missouri residents whose ObTape-related treatment took place in Missouri, and the parties agree that Missouri law applies to their claims.

Mentor seeks summary judgment on both Plaintiffs' claims for breach of express warranty and fraudulent concealment. Mentor also seeks summary judgment on Clinton's breach of the continuing duty to warn claim. The Court will evaluate each of Mentor's summary judgment arguments in turn.

##### **I. Breach of Express Warranty**

Missouri has a four-year statute of limitations for breach of express warranty claims. Mo. Ann. Stat. § 400.2-725(1). "A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach." *Id.* § 400.2-725(2). If this statute of limitations applies to Plaintiffs' breach of express warranty claims, the claims are

time-barred because Plaintiffs' ObTape was delivered in December 2004 and neither Plaintiff filed her action within four years.

Plaintiffs argue that the four-year statute of limitations does not apply to their breach of express warranty claims. In support of this argument, Plaintiffs point to Missouri case law following *Greenman v. Yuba Power Products, Inc.*, 59 Cal.2d 57 (1963) and adopting strict liability in tort for products liability cases. *State ex rel. Apco Oil Corp. v. Turpin*, 490 S.W.2d 400, 405 (Mo. Ct. App. 1973) ("A products liability case is now considered to be tortious and any recovery is really in tort."). They also pointed to precedent regarding the applicable statute of limitations for *implied* warranty cases. *E.g., Witherspoon v. Gen. Motors Corp.*, 535 F. Supp. 432, 434 (W.D. Mo. 1982).

As the Court previously observed, *Greenman* adopted the doctrine of strict liability and concluded that the procedural requirements of a warranty claim cannot defeat strict products liability in tort. *Greenman*, 59 Cal.2d at 61-62 (explaining that strict liability in tort is not based on the law of contract warranties). Plaintiffs did not point the Court to any authority that Missouri's adoption of strict liability in tort changes the applicable statute of limitations for a plaintiff attempting to proceed under a *contract* theory of recovery. In the absence of such authority, the Court concludes that

Plaintiffs' breach of express warranty claims are time-barred, and summary judgment is therefore granted as to their breach of express warranty claims. As a practical matter, Plaintiffs' breach of express warranty claims appear to be nearly identical to their strict liability failure to warn claims, and Mentor did not move for summary judgment on those claims.

## **II. Fraudulent Concealment**

Mentor also seeks summary judgment on Plaintiffs' fraudulent concealment claims, which are based on their assertion that Mentor concealed material facts about ObTape from their implanting physicians and that they would not have undergone the ObTape procedure if Mentor had disclosed ObTape's true risks to their implanting physicians. "Silence or nondisclosure becomes misrepresentation only when there is a duty to speak." *Bohac v. Walsh*, 223 S.W.3d 858, 864 (Mo. Ct. App. 2007). Missouri imposes "a duty to disclose information when there is a relation of trust and confidence between the parties or when one of the parties has superior knowledge or information not within the fair and reasonable reach of the other party." *Id.* Mentor asserts that there was no "duty to speak" here because no fiduciary relationship existed between Mentor and Plaintiffs.

Under Missouri law, the manufacturer of a prescription device "has 'a duty to properly warn the doctor of the dangers



involved and it is incumbent upon the manufacturer to bring the warning home to the doctor.'" *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) (quoting *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146 (Mo. 1967)). In other words, "the manufacturer of prescription . . . products discharges its duty to warn by providing the physician with information about risks associated with those products." *Id.* Thus, it is clear that Mentor had a duty to warn each Plaintiff's implanting physician about the risks associated with ObTape so that the physician could decide whether to implant it in his patient. The Court declines to find that Plaintiffs' fraudulent concealment claims fail for lack of a fiduciary relationship.

Mentor argues that even if it had a duty to disclose facts that it allegedly concealed, Woolf has not pointed to any evidence to create a genuine fact dispute on causation. The Court disagrees. Woolf pointed to evidence that Mentor provided certain information about ObTape's risks to her implanting physician, that Woolf's implanting physician routinely shared such information with his patients, and that Woolf would not have consented to the procedure had she known ObTape's true risks. For these reasons, the Court denies summary judgment as to Plaintiffs' fraudulent concealment claims.

### **III. Continuing Duty to Warn**

Finally, Mentor seeks summary judgment on Clinton's continuing duty to warn claim. Mentor argues that Missouri has not recognized such a claim. Mentor also argues that even if Missouri were to recognize such a claim, Clinton has not presented sufficient evidence of causation. Pretermitted the question whether Missouri recognizes a continuing duty to warn claim, the Court finds that Clinton has not presented sufficient evidence to create a genuine factual dispute on causation.

Clinton argues that if Mentor had provided adequate post-implant warnings about ObTape, one of her doctors could have removed the ObTape before they ultimately did, thus preventing some of her injuries. Clinton does not base her continuing duty to warn claim on Mentor's alleged failure to provide adequate post-implant warnings to her implanting physician, Dr. Saba. She did not argue or point to any evidence that her post-implant treatment would have been different if Mentor had provided a post-implant warning to Dr. Saba—such as evidence that Dr. Saba would have taken a different approach to her treatment or evidence that Dr. Saba would have passed the warning along to Clinton and that Clinton's injuries would have been mitigated if he had done so.

Rather, Clinton relies exclusively on the testimony of Dr. Mazuski to establish causation on her continuing duty to warn

claim. According to Clinton, if Dr. Mazuski, a general surgeon, had known of a potential connection between ObTape and Clinton's groin and leg pain when he treated her in 2005, it would have been an option for him to remove the ObTape. Again, it is not clear from the present record whether Dr. Mazuski even knew that Clinton had been implanted with ObTape when he treated her in 2005. As discussed above, the manufacturer of a prescription medical device "has 'a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor.'" *Doe*, 3 S.W.3d at 419 (quoting *Krug*, 416 S.W.2d at 146). Thus, Mentor had a duty to warn Clinton's implanting physician about the risks associated with ObTape so that he could decide whether to implant her with the product. That duty to warn would also likely extend to doctors who regularly treat patients with suburethral sling products, such as urologists and gynecologists. But Clinton did not point to any authority that Mentor had a duty to warn all physicians everywhere of the risks of ObTape. And she did not point the Court to any authority that Mentor had a duty to warn Dr. Mazuski, a general surgeon who does not have any clinical experience with suburethral slings and does not make decisions regarding the implant or explant of suburethral slings, and the Court found none. For these reasons, Clinton cannot rely on Dr. Mazuski's testimony to establish causation. Moreover, even if

Missouri law did require Mentor to warn Dr. Mazuski of the risks associated with ObTape, there is no evidence that such a warning would have made a difference in Dr. Mazuski's treatment of Clinton because Clinton did not point to any evidence establishing that Dr. Mazuski knew in 2005 that Clinton had been implanted with ObTape.

Again, Clinton does not argue that Mentor's failure to provide adequate post-implant warnings to Dr. Saba caused her injuries. She also does not argue that Mentor's failure to provide adequate post-implant warnings to Dr. Bullock and Dr. Klutke—the two urologists who performed Clinton's revision surgeries—caused her injuries. Both Dr. Bullock and Dr. Klutke tried to remove as much of the ObTape as they could, which Clinton agrees they should have done. Clinton pointed to no evidence that Dr. Bullock and Dr. Klutke would have taken a different approach if they had been given different post-implant warnings or that a different approach by these two doctors in 2007 and 2008 would have mitigated her injuries. For all of these reasons, Clinton's continuing duty to warn claim fails.

#### CONCLUSION

**Andrea Clinton.** Mentor's motion for partial summary judgment (ECF No. 49 in 4:12-cv-245) is granted as to Clinton's breach of express warranty and continuing duty to warn claims. Mentor's summary judgment motion is denied as to Clinton's

fraudulent concealment claim. That claim, along with her claims for negligence, strict liability - design defect, strict liability - manufacturing defect, strict liability - failure to warn, breach of implied warranties, fraudulent misrepresentation, and negligent misrepresentation remain pending for trial.

**Bobbie Jo Woolf.** Mentor's motion for partial summary judgment (ECF No. 43 in 4:12-cv-252) is granted as to Woolf's claims for breach of express warranty, breach of implied warranty, fraudulent misrepresentation, and negligent misrepresentation. Mentor's motion is denied as to Woolf's fraudulent concealment claim. That claim, along with Woolf's claims for negligence, strict liability - design defect, strict liability - manufacturing defect, and strict liability - failure to warn, remain pending for trial.

**Within seven days of the date of this Order, the parties shall notify the Court whether the parties agree to a Lexecon waiver.**

IT IS SO ORDERED, this 29th day of February, 2016.

s/Clay D. Land  
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CLAY D. LAND  
CHIEF U.S. DISTRICT COURT JUDGE  
MIDDLE DISTRICT OF GEORGIA